Application No. 10/045,292

Attorney Docket No.: 09797.0004-00

## **REMARKS**

## I. Status of the Claims

Claims 1-5, 35, 36, 39-42, 44, 50, 51, 54-57, and 59 are under consideration in this application and stand rejected. Claims 6-34, 37, 38, 43, 45-49, 52, 53, and 58 were withdrawn from consideration by the Examiner as being directed to non-elected subject matter and are herewith canceled without prejudice to or disclaimer of the subject matter recited therein.

By this Amendment, claims 1, 35, 39-42, 44, and 50 are amended and new claims 60-70 are added. Claim 1 is amended to add provisos and to delete "Flaviviridae." The deleted subject matter is added as new claims 60-65. Claims 35 and 50 are amended to add a proviso. Claims 39, 41, and 42 are amended to delete "Flaviviridae." Claim 40 is amended to delete "or abnormal cellular proliferation." Claim 44 is amended to depend on claims 60-62, 64, and 65. New claim 66 is added. Support for claim 66 may be found, for example, at pages 51, 186, and 195 of the specification (compound "BO"). New claims 67-70 further recite compounds within the scope of claim 1 and support may be found, for example, in original claim 1. No new matter has been added by the above amendments.

Applicant acknowledges the withdrawal of the prior claim objections and rejections under U.S.C. § 112, first and second paragraphs. Applicant also acknowledges the withdrawal of the prior rejection under U.S.C. § 102(e) over U.S. Patent Application No. 2004/0110718 to Devos et al.

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## II. Rejections Under 35 U.S.C. § 102

In this Office Action, the Examiner maintains the rejection of claims 1-5, 35, 44, and 50 under 35 U.S.C. § 102(a), as allegedly being anticipated by Filippini et al., "Can HCV affect the efficacy of anti-HIV treatment?" Archives of Virology, 145(5), 937-944, May 2000 ("Filippini"). Office Action at 3-5. The Examiner continues to assert that "Filippini et al. disclose a method of treating patients with HCV [with] compositions comprising Zalcitabine ..., which is known to be 2'-3'-dideoxycytidine." *Id.* at 4.

Applicant respectfully submits that the instant amendments render the rejection over Filippini moot. Claim 1, as currently amended, does not recite compounds for the treatment of a *Flaviviridae* viral infection. Claims 35 and 50 are amended to exclude 2'-3'-dideoxycytidine for the treatment of HCV virus infections.

In addition, the Examiner rejects claims 1-5, 35-36, 39-42, 44, 50-51, 54-57, and 59 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,812,219 to LaColla et al. ("LaColla"). See Office Action at 5. The Examiner asserts "LaColla et al. disclose methods of treating flavivirus or pestivirus infections, including HCV, by administering various modified nucleosides" and cites to compounds VII-XVIII in columns 7-11. *Id.* According to the Examiner, "[t]he art teaches that overlapping compounds are administered to the same population to treat the same disorders. Due to the extremely large genus instantly claimed, it is obvious that the claimed genus is

<sup>&</sup>lt;sup>1</sup> In the first Office Action, the Examiner asserted Filippini under 35 U.S.C. § 102(b), but in response to Applicant's argument submitted on July 3, 2007, the Examiner now asserts Filippini as a § 102(a) reference. See Office action at 4.

indeed overlapping with the compounds used to treat HCV as set forth in [LaColla]." *Id.*Applicant respectfully disagrees.

"A claim is anticipated only if <u>each and every element</u> as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. § 2131 (quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)) (emphasis added). Further, a rejection under § 102 is proper only when the claimed subject matter is <u>identically</u> described or disclosed in the prior art. *In re Arkley*, 455 F.2d 586, 587 (C.C.P.A. 1972) (emphasis added). The identical invention must be described in as complete detail as is contained in, and must be arranged as required by, the claim. M.P.E.P. § 2131.

When considering a reference under § 102, one may look to the preferred embodiments to determine which compounds can be anticipated. *In re Petering*, 301 F.2d 676, 133 U.S.P.Q. 275 (C.C.P.A. 1962). "When the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific compound, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated." M.P.E.P. § 2131.02 (citing *Ex parte A*, 17 U.S.P.Q.2d 1716 (Bd. Pat. App. & Inter. 1990)). In order to anticipate, a prior art reference must "clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without any need for picking, choosing, and combining various disclosures . . . ." *In re Arkley*, 455 F.2d 586, 587,172 U.S.P.Q. 524, 526 (C.C.P.A.

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1972). The reference must therefore provide a certain degree of precision with respect to the specific compound claimed.

Applicant respectfully submits that LaColla's compositions, in particular those identified by the Examiner in columns 7-11, do not anticipate Applicant's claimed compositions because too much improper picking and choosing of substituents would be required to reach the presently claimed compositions. *See* M.P.E.P. § 2131.02. Formula (XVI) of LaColla, for example, has eight variable substituents, of which R¹ has at least 11 possibilities, R⁶ has at least 25 possibilities, Rⁿ and Rⁿ each independently have at least 25 possibilities, Rfl and R¹0 each independently have at least 5 possibilities, and X has at least 4 possibilities. LaColla, col. 9, line 40 to col. 10, line 19. In addition, in LaColla's compounds VII-XVIII, the "base" described is defined as "a purine or pyrimidine base as defined herein." *See*, *e.g.*, Column 7, line 41. In its definition of "base," LaColla defines at least 40 possibilities. LaColla does not disclose bases of the presently claimed compounds where, for example, the N⁴ or S⁴ position on a pyrimidine base is substituted.

In fact, no species or subgenus specifically disclosed in LaColla is fully encompassed by the present claims. Furthermore, no direction is offered by the reference to pick and choose the particular substituents to arrive at the presently claimed compounds. As noted above, the Federal Circuit and its predecessor have made it clear that such an imprecise disclosure involving numerous decision-making steps cannot be anticipation.

Accordingly, Applicant respectfully requests that this rejection be withdrawn.

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In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

If the Examiner believes a phone call would be useful in resolving outstanding issues, if any, he is respectfully invited to contact the undersigned at 202-408-4069.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: April 30, 2008

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